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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|--------------------------|----------------------|------------------------|------------------|
| 09/647,377 | 02/12/2001 | Andre Rosenthal | 147-211P | 7286 |
| 2292 | 7590 04/09/2004 | | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH | | | PRIEBE, SCOTT DAVID | |
| PO BOX 74 FALLS CH | 7 URCH, VA 22040-0747 | | ART UNIT | PAPER NUMBER |
| THEES CIT | onen, vii 22010 0717 | , | 1632 | |
| | | | DATE MAILED: 04/09/200 | 4 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|--|---|-----------------------------------|-------------------------|--|--|--|
| Office Action Summary | | 09/647,377 | ROSENTHAL ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Scott D. Priebe | 1632 | | | |
| Period fo | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ | 1)⊠ Responsive to communication(s) filed on <u>15 March 2004</u> . | | | | | |
| 2a) <u></u> | This action is FINAL . 2b)⊠ This | s action is non-final. | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposit | ion of Claims | | | | | |
| 4) Claim(s) 1-41 is/are pending in the application. 4a) Of the above claim(s) 9-11,14-19,22,27,28 and 30-35 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-8,12,13,20,21,23-26,29 and 36-41 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicati | ion Papers | | | | | |
| 9)⊠ The specification is objected to by the Examiner. 10)⊠ The drawing(s) filed on 28 April 2003 is/are: a) accepted or b)⊠ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)[| The oath or declaration is objected to by the Ex | xaminer. Note the attached Office | Action or form PTO-152. | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notic 3) Inforr | te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | Paper No(s)/Mail Da | | | | |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 15 March 2004 has been entered. Applicant has indicated that a supplemental response would be forthcoming. However, no supplemental response has been received. Applicant is reminded that all amendments or supplemental replies should be filed cotemporaneous with an RCE request (see MPEP 706.07(h), III.D., also MPEP 714.05). The response to the final rejection filed 20 Oct. 2003 has been entered, and constitutes the required submission.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

Claims 9-11, 14-19, 22, 27, 28 and 30-35 in their entirety and claims 1-8, 12, 13, 20, 21, 23-26, and 37-41 as directed to SEQ ID NOs 13 and 14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there

being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12. The requirement was made FINAL in the Office action of 9/3/02.

Drawings

The corrected or substitute drawings were received on 3/10/03 (or 4/28/03). These drawings are not acceptable for the reasons set forth on the PTO-948 filed 13 June 2003, and the conditions for accepting color photographs have not been met. Specifically, the papers filed lack three sets of color drawings or color photographs, as appropriate. Color photographs will be accepted if the conditions for accepting color drawings have been satisfied. With respect to Figures 1 and 8 filed 4/28/03, the color photographs have or are falling off of the sheet, which is unacceptable. Figures 1 and 8 as filed 3/10/03 would be acceptable.

Specification

The disclosure is objected to because of the following informalities: The 'Brief Description' of Figures 2a-2m fails to comply with 37 C.F.R. §§ 1.821 (d) for failing to identify the disclosed sequences by their assigned SEQ ID NO (alternatively corrected drawings, which includes the assigned SEQ ID NOs, could be filed).

Appropriate correction is required.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends from claim 5 or 6, both of which are directed to a vector. However, claim 7 is directed to the nucleic of claims 5 or 6, which is only part of the vector. Consequently, claim 7 may be infringed without infringing claims 5 or 6, e.g. a cell transformed with a DNA consisting of SEQ ID NO: 9. Note that a vector may contain more than the recited nucleic acid molecule. This objection would be overcome by amending the claim to —a host cell transformed with the vector of ...—.

Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim, in this case claim 5. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 101 & 112

Claims 1-8, 12, 13, 20, 21, 23-26, 29 and 36-41 remain rejected under 35 U.S.C. 101 for the reasons of record set forth in the Office action of 9/3/02, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Also, claims 1-8, 12, 13, 20, 21, 23-26, 29 and 36-41 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed 20 Oct. 2003 have been fully considered but they are not persuasive for the reasons set forth the Advisory Action of 29 Oct. 2003.

Claims 1-8, 12, 13, 20, 21, 23-26, 29, and 36-41 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 9/3/02, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 20 Oct. 2003 have been fully considered but they are not persuasive for the reasons set forth the Advisory Action of 29 Oct. 2003. As indicated in the Advisory Action, the new grounds of rejection of claim 40 set forth in the Office action of 13 June 2003 have been overcome. The remaining grounds of rejection are maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. (The new objections to claim 7 have no effect here.) Accordingly, **THIS**ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe Primary Examiner

Scott D. Crube

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